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Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-1118

PETER H. FORSHAM, ET AL.,

Petitioners,

v.

JOSEPH A. CALIFANO, JR., SECRETARY OF HEALTH, EDUCATION, AND WELFARE, ET AL.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF IN OPPOSITION OF RESPONDENT, DR. CHRISTIAN R. KLIMT

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The respondent, Dr. Christian R. Klimt, respectfully requests that this Court deny the petition for writ of certiorari, seeking review of the opinion of the United States Court of Appeals for the District of Columbia Circuit in this case. That opinion is reported at 587 F.2d 1128 (D.C. Cir. 1978).

QUESTION PRESENTED

Do raw data of a research study conducted by non-federal institutions, but funded by federal grants,

constitute "agency records" within the meaning of the Freedom of Information Act when the Government never controlled the research and never owned or possessed the raw data?

STATEMENT OF THE CASE

The petitioners seek review of the decision of the United States Court of Appeals for the District of Columbia Circuit that research data compiled by a non-federal group receiving money under a federal grant program do not become "agency records" under the Freedom of Information Act, 5 U.S.C. §552 (1976), merely because the Federal Government has funded the research program and has the authority to demand the production of the research data.

In 1959, twelve participating medical school clinics throughout the country (none of which are federal agencies or institutions) and a coordinating center at the University of Maryland formed the University Group Diabetes Program (the "Program") to conduct a long-term clinical study of the treatment of diabetes. The purpose of the study was to determine the relationship between the control of blood sugar in patients suffering from adult onset diabetes and the development of complications from this disease. To fund the study, the institutions participating in the Program obtained thirteen separate grants from the National Institute of Arthritis, Metabolism, and Digestive Diseases (the "Institute") of the National Institutes of Health; however, the physicians and scientists working for the participating institutions planned, designed, and conducted the study without the supervision or control of any federal agency.

The Program compiled data from the treatment of over 1,000 diabetic patients from 1961 to 1970 under four different treatment regimens; a fifth regimen was

included in 1963. Analyzing the data, the Program investigators concluded, among other things, that the administration of oral hypoglycemic drugs to certain adult onset diabetics led to a greater death rate from cardiovascular disease than was found in the groups not treated with such drugs. These findings were published in the Journal of the American Diabetes Association in December 1970.

In 1974, the petitioners asked the Institute for the raw data on which the study was based. Various officials of the Department of Health, Education, and Welfare advised them that, because no federal agency had any of the raw data, they were not able to grant the request. Subsequently, on July 5, 1975 the Commissioner of the Food and Drug Administration issued a notice of proposed regulations to require manufacturers of hypoglycemic drugs to include appropriate warnings in their labels. 40 Fed. Reg. 28,587 (1975).

Shortly thereafter, the petitioners filed an action in the United States District Court for the District of Columbia against the Secretary of Health, Education, and Welfare, other federal officials, and Dr. Klimt, Director of the Program's coordinating center at the University of Maryland, to obtain the research data. On February 5, 1976 the district court denied the petitioners' motion for summary judgment and granted the federal respondents' motion to dismiss. On appeal, the United States Court of Appeals for the District of Columbia Circuit affirmed.[1]

[1] The respondent does not adopt the petitioners' statement of the case and has not responded at length to it because much of it is irrelevant to the issues before this Court. For example, the petitioner's alleged need for or interest in obtaining the data is irrelevant to whether the data are "agency records." NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 143 n.10 (1975). The decision of the court of appeals accurately states the background facts in this case.

REASONS FOR DENYING THE WRIT

The court of appeals held that the raw data gathered during the study by the Program, formed by thirteen non-federal institutions, were not federal agency records within the meaning of the Freedom of Information Act. The court reasoned that the funding of the study by the Federal Government, which exercised no control over the performance of the study, did not convert the Program's participants into federal agencies. The court also concluded that, although the Federal Government may have the right of access to the raw data, the Freedom of Information Act did not require the Federal Government to exercise whatever right of access it may have to obtain the raw data and thereby to make them "agency records." In addition, the court held that the Government's right of access by itself did not transform the data into "agency records."

Thus, the court determined a narrow issue of interpretation of the Freedom of Information Act. Because the decision of the court of appeals does not conflict with the decisions of any federal court on this issue, because it is in complete harmony with the principles enunciated by this Court and lower federal courts, and because the issue in this case is not an important question of federal law requiring resolution by this Court, the petition for a writ of certiorari should be denied.[2]

[2] The respondent is aware that, contemporaneously with its consideration of this petition, the Court is considering petitions seeking review of the unrelated decision of the United States Court of Appeals for the District of Columbia Circuit in Reporters Committee for Freedom of Press v. Vance, No. 78-1207 (5th Cir. Nov. 7, 1978), *petitions for cert. filed*, No. 78-1088 (Jan. 8, 1979); No. 78-1217 (____, 1979). The decision of the court of appeals in *Vance* affirmed the judgments of the district court. The district court held that transcriptions of telephone conversations between former Secretary of State Kissinger and others, which were produced in accordance with regulations of the Department of State and on Government time with the aid of departmental employees, equipment, materials and other public resources, were the property of the United States and not the personal property of Mr. Kissinger and that the plaintiffs had withdrawn their claim to Mr. Kissinger's notes of conversations conducted in his capacity as National Security Advisor. Reporters Committee for Freedom of Press v. Vance, 442 F. Supp. 383 (D.D.C. 1977).

It is clear that the petitions in the cases concerning Mr. Kissinger's notes involve entirely different issues from the question presented in this case. Accordingly, this Court's determination of whether to grant review in those cases should not affect its consideration of the petition in this case.

I.

THE DECISION OF THE COURT OF APPEALS DOES NOT CONFLICT WITH THE HOLDINGS OR PRINCIPLES OF THE DECISIONS OF THIS COURT OR OTHER FEDERAL COURTS.

In determining that the raw data of the Program's study are not agency records within the meaning of the Freedom of Information Act, the court of appeals relied on well-established principles of law stated by this Court, the courts of appeals, and district courts. The court of appeals neither deviated from these principles nor announced new principles in conflict with any of these decisions. For this reason alone, the decision of the court of appeals should not be reviewed by this Court.

For example, the United States District Court for the Southern District of New York reached an identical conclusion that the raw data of the Program's study were not agency records within the meaning of the Freedom of Information Act. *Ciba-Geigy Corp. v. Mathews*, 428 F. Supp. 523 (S.D.N.Y. 1977). In that case, the district court concluded that neither the Program nor the individuals or institutions participating in the Program had any authority in law to make decisions for a federal agency. The court also held that the degree of governmental involvement in the opera-

tions of the Program was insufficient to make the Program an agency for purposes of the Act. 428 F. Supp. at 528.

This conclusion is completely consistent with the purpose of the Freedom of Information Act. As the district court stated in *Lombardo v. Handler*, 397 F. Supp. 792, 802 (D.D.C. 1975), *aff'd*, 546 F.2d 1043 (D.C. Cir. 1976) (*mem.*), *cert. denied*, 431 U.S. 932 (1977):

> The strength of the [Act] is the concept of public accountability for the operation of federal agencies. It was not intended to be applied directly to private entities which merely contract with the government to conduct studies.

In *Lombardo*, the court held that the National Academy of Sciences and its committee on motor vehicle emissions, which had contracted with the Administrator of the Environmental Protection Agency to conduct studies relating to certain emission standards established under the Clean Air Act, were not federal agencies.

When faced with a question of whether a particular entity is a federal agency within the meaning of the Freedom of Information Act, the courts have determined whether the entity has any authority in law to make decisions, *Washington Research Project, Inc. v. Department of Health, Education, and Welfare*, 504 F.2d 238, 248 (D.C. Cir. 1974), *cert. denied*, 421 U.S. 963 (1975) (holding that initial review groups composed of non-governmental specialists established to assist the Government in evaluating proposals for research grants are not federal agencies), or whether the entity is subject to substantial federal control over its day-to-day operations, *Rocap v. Indiek*, 539 F.2d 174, 177 (D.C. Cir. 1976) (holding that the Federal Home Loan Mortgage Corporation is a federal agency). Similarly, whether a particular entity is a federal agency for other purposes generally depends upon the degree of control that the

Federal Government exercises over that entity. *United States v. Orleans*, 425 U.S. 807, 818 (1976) (holding that a local community action agency is not a federal agency and that its employees are not federal employees within the meaning of the Federal Torts Claims Act); *Spark v. Catholic University*, 510 F.2d 1277, 1282 (D.C. Cir. 1975), and *Wahba v. New York University*, 492 F.2d 96, 102 (2d Cir.), *cert. denied*, 419 U.S. 874 (1974) (both holding that private universities are not subject to constitutional restrictions applicable to the Government). Furthermore, as these cases hold, the mere receipt of federal funds by the non-governmental entity does not convert a private entity into a federal agency. The court of appeals did nothing more than correctly apply these principles to the facts in this case.

Before the court of appeals and in their petition, the petitioners suggest that the right of access to the raw data which the officials of the Department of Health, Education, and Welfare enjoy pursuant to 45 C.F.R. § 74.23(a) (1977) makes the raw data agency records. As the court of appeals concluded, this argument is without merit. There is nothing in the Freedom of Information Act to suggest that a federal agency's right to obtain information in private hands transforms that information into agency records.

Furthermore, this Court recognized this very principle in *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132 (1975). In *Sears*, this Court held that the Freedom of Information Act did not compel federal agencies to produce or create material or to write opinions in cases in which they would not otherwise be required to do so.

> [The Act] only requires the disclosure of certain documents which the law requires the agency to prepare or which the agency has decided for its own reasons to create.

Id. at 161-62. Consequently, because there is no conflict between the decision of the court of appeals and the decisions of this Court and other federal courts, this Court should deny the writ of certiorari.

II.

THE ISSUE DECIDED BY THE COURT OF APPEALS IS NOT AN IMPORTANT QUESTION OF FEDERAL LAW REQUIRING RESOLUTION BY THIS COURT.

Notwithstanding the petitioners' hyperbole about broad implications for millions of diabetic patients, petition at 14, the decision of the court of appeals has very little significance for diabetic patients who may be affected by the actions of the Secretary of Health, Education, and Welfare or the Commissioner of the Food and Drug Administration.

The court of appeals itself recognized the limited impact of its decision. It specifically stated that its ruling had no effect on whether the petitioners would have a right of access to the raw data in any existing or future proceedings by the Commissioner of the Food and Drug Administration. Furthermore, it recognized that the appropriateness of the action of the Commissioner and the availability of the raw data in any proceedings before the Commissioner were distinctly different issues from the issue before the court. 587 F.2d at 1134.

In addition, the availability or non-availability of the data to the petitioners has very little direct impact upon the action of the Commissioner in requiring manufacturers of hypoglycemic drugs to include certain warnings in their labels. The Commissioner decided to issue the proposed regulation not because he had accepted without question the results of the study but rather, even assuming certain flaws in the Program's study, the findings of the study did raise a serious

question about the risk associated with the use of such drugs. 40 Fed. Reg. 28,587, 28,591 (1975).

Even if the petitioners were to obtain access to the raw data and were able to derive different conclusions from that data than did the Program, the Commissioner would not be required to rescind the proposed regulations. The Commissioner might have to evaluate the analysis which the petitioners would propose, but he would have the responsibility to make a judgment based upon all of the available evidence and the opinion of the experts who interpreted that evidence. Even with a contrary analysis by the petitioners, the Commissioner might still require the warnings, on the basis of the Program's study. Thus, although the outcome of the continuing debate in which this case plays a small part may have broad implications for diabetic patients, the impact of the decision of the court of appeals is itself negligible. In view of the unanimity of federal court decisions on the principles by which the court of appeals was guided, this case does not present a significant question of federal law which this Court should address.

CONCLUSION

For these reasons, this Court should deny the petition for a writ of certiorari.

Respectfully submitted,

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